ABSTRACT OF THE INVENTION

A system, method, and computer-readable medium for the collecting and storing of environmental data, and generating a user report of the environmental data, the user report providing document compliance with U.S. Food and Drug Administration requirements. The collected and stored environmental data includes a wide variety of manufacturing facility parameter data, including but is not limited to, the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s).

Banner & Witcoff. Ltd Ten South Wacker Drive Suite 3000 Chicago, IL 60606 Telephone: (312) 463-5000